

EXHIBIT 12



Original Article

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Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift™ technique)—a case series multicentric study

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Abstract

Our goal was to report the preliminary results of a transvaginal mesh repair of genital prolapse using the Prolift™ system. This retrospective multicentric study includes 110 patients. All patients had a stage 3 (at the hymen) or stage 4 (beyond the hymen) prolapse. Total mesh was used in 59 patients (53.6%), an isolated anterior mesh in 22 patients (20%) and an isolated posterior mesh in 29 patients (26.4%). We report one bladder injury sutured at surgery and two haematomas requiring secondary surgical management. At 3 months, 106 patients were available for follow-up. Mesh exposure occurred in five patients (4.7%), two of them requiring a surgical management. Granuloma without exposure occurred in three patients (2.8%). Failure rate (recurrent prolapse even asymptomatic or low grade symptomatic prolapse) was 4.7%. According to the perioperative and immediate post-operative results, Prolift™ repair seems to be a safe technique to correct pelvic organ prolapse. Anatomical and functional results must be assessed with a long-term follow-up to confirm the effectiveness and safety of the procedure.

Keywords

Pelvic organ prolapse Vaginal surgery Mesh Polypropylene Mesh exposure Synthetic implants



Concepts found in this article

Mesh Exposure

Transvaginal Mesh Repair

Vaginal Vault Prolapse

Uterine Prolapse

Urinary Incontinence

Vaginal Hysterectomy

Recurrent Prolapse

Sacrospinous Ligament

Posterior Mesh

Mesh Retraction

Genital Prolapse

Posterior Vaginal Wall

TVT-O Procedure

Mesh Resection

Anterior Mesh

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Page 1 of 94

References

1. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 89:501–506
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=9083302) *CrossRef* ([http://dx.doi.org/10.1016/S0029-7844\(97\)00058-6](http://dx.doi.org/10.1016/S0029-7844(97)00058-6))
2. Clark AL, Gregory T, Smith VJ, Edwards R (2003) Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. *Am J Obstet Gynecol* 189:1261–1267
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=14634551) *CrossRef* ([http://dx.doi.org/10.1067/S0002-9378\(03\)00829-9](http://dx.doi.org/10.1067/S0002-9378(03)00829-9))
3. Whiteside JL, Weber AM, Meyn LA, Walters MD (2004) Risk factors for prolapse recurrence after vaginal repair. *Am J Obstet Gynecol* 191:1533–1538
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=15547521) *CrossRef* (<http://dx.doi.org/10.1016/j.ajog.2004.06.109>)
4. Cosson M, Boukerrou M, Lambaudie E, Lobry P, Crépin G, Ego A (2003) [Biomechanics of stress distribution and resistance of biological tissues: why use prostheses for the cure of genital prolapse?] *J Gynecol Obstet Biol Reprod (Paris)* 32:329–337
5. Brenner J (1995) Mesh materials in hernia repair. In: Schumpelick V, Wantz GE (eds) *Inguinal hernia repair. Expert meeting on hernia surgery, St Moritz, 1994.* Karger, Basel, pp 172–179
6. Gadonneix P, Ercoli A, Scambia G, Villet R (2005) The use of laparoscopic sacrocolpopexy in the management of pelvic organ prolapse. *Curr Opin Obstet Gynecol* 17:376–380
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=15976543)
7. Benson JT, Lucente V, McClellan E (1996) Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: prospective randomized study with long-term outcome evaluation. *Am J Obstet Gynecol* 175:1418–1421
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=8987919) *CrossRef* ([http://dx.doi.org/10.1016/S0002-9378\(96\)70084-4](http://dx.doi.org/10.1016/S0002-9378(96)70084-4))
8. Maher CF, Qatawneh AM, Dwyer PL, Carey MP, Cornish A, Schluter PJ (2004) Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. *Am J Obstet Gynecol* 190:20–26
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=14749629) *CrossRef* (<http://dx.doi.org/10.1016/j.ajog.2003.08.031>)
9. Maher C, Baessler K (2006) Surgical management of anterior vaginal wall prolapse: an evidencebased literature review. *Int Urogynecol J Pelvic Floor Dysfunct* 17:195–201
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=15915320) *CrossRef* (<http://dx.doi.org/10.1007/s00192-005-1296-3>)
10. Iglesia CB, Fenner DE, Brubaker L (1997) The use of mesh in gynecologic surgery. *Int Urogynecol J Pelvic Floor Dysfunct* 8:105–115
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=9297599)
11. Julian M (1996) The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior vaginal wall. *Am J Obstet Gynecol* 175:1472–1475
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=8987927) *CrossRef* ([http://dx.doi.org/10.1016/S0002-9378\(96\)70092-3](http://dx.doi.org/10.1016/S0002-9378(96)70092-3))
12. Ulmsten U, Johnson P, Rezapour M (1999) A three-year follow-up of tension-free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* 10:345–350
13. Kuuva N, Nilsson CG (2002) A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand* 81:72–77
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=11942891) *CrossRef*

(<http://dx.doi.org/10.1034/j.1600-0412.2002.810113.x>)

14. Cosson M, Boukerrou M, Lobry P, Crépin G, Ego A (2003) [Mechanical properties of biological or synthetic implants used to cure genital prolapse and stress incontinence: what is the ideal material?] *J Gynecol Obstet Biol Reprod (Paris)* 32:321–328
15. Debodinance P, Berrocal J, Clavé H, Cosson M, Garbin O, Jacquetin B, Rosenthal C, Salet-Lizée D, Villet R (2004) [Changing attitudes on the surgical treatment of urogenital prolapse: birth of the tension-free vaginal mesh]. *J Gynecol Obstet Biol Reprod (Paris)* 33:577–588
16. Richardson DA, Scotti RJ, Ostergard DR (1989) Surgical management of uterine prolapse in young women. *J Reprod Med* 34:388–392
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=2661812) CrossRef
(<http://dx.doi.org/10.1016/j.eururo.2003.09.003>)
17. Fatton B, Jacquetin B (2003) Sacrospinous fixation according to Richter. In Stanton SL, Zimmern PZ (eds) *Female pelvic reconstructive surgery*, Springer, Berlin Heidelberg New York, pp 192–199
18. de Leval J (2003) Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol* 44:724–730
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=14644127) CrossRef
(<http://dx.doi.org/10.1016/j.eururo.2003.09.003>)
19. Dwyer PL, O'Reilly BA (2004) Transvaginal repair of anterior and posterior compartment prolapse with Atrium polypropylene mesh. *BJOG* 111:831–836
20. Nygaard IE, McCreery R, Brubaker L, Connolly A, Cundiff G, Weber AM, Zyczynski H, Pelvic Floor Disorders Network (2004) Abdominal sacrocolpopexy: a comprehensive review. *Obstet Gynecol* 104:805–823
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=15458906)
21. Cosson M, Caquant F, Collinet P, Rosenthal C, Clave H, Debodinance P, Garbin O, Berrocal J, Villet R, Jacquetin B (2005) Prolift mesh (Gynecare) for pelvic organ prolapse surgical treatment using the TVM group: a retrospective study of 687 patients. Communication in the ICS meeting, Montreal, 31 August 2005
22. Culligan PJ, Murphy M, Blackwell L, Hammons G, Graham C, Heit MH (2002) Long-term success of abdominal sacral colpopexy using synthetic mesh. *Am J Obstet Gynecol* 187:1473–1480
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=12501049) CrossRef
(<http://dx.doi.org/10.1067/mob.2002.129160>)
23. Achtari C, Hiscock R, O'Reilly BA, Schierlitz L, Dwyer PL (2005) Risk factors for mesh erosion after transvaginal surgery using polypropylene (Atrium) or composite polypropylene/polyglactin 910 (Vipro II) mesh. *Int Urogynecol J Pelvic Floor Dysfunct* 16:389–394
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=15657636) CrossRef
(<http://dx.doi.org/10.1007/s00192-004-1272-3>)
24. Milani R, Salvatore S, Soligo M, Pifarotti P, Meschia M, Cortese M (2005) Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. *BJOG* 112:107–111
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=15663408) CrossRef
(<http://dx.doi.org/10.1111/j.1471-0528.2004.00332.x>)
25. Dwyer PL, O'Reilly B (2005) Dyspareunia following vaginal surgery for prolapse using polypropylene mesh. Re: paper by Milani et al. *BJOG* 112:1164
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=16045540)
26. Silva WA, Karram MM (2005) Scientific basis for use of grafts during vaginal reconstructive procedures. *Curr Opin Obstet Gynecol* 17:519–529
PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Abstract&list_uids=16141767) CrossRef
(<http://dx.doi.org/10.1097/01.gco.0000180156.64879.00>)

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